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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,130	06/19/2003	John F. Kay	02738.0030.CPUS02	5589
22910	7590	09/26/2005	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/600,130

Applicant(s)

KAY ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8-30-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 - 48 is/are pending in the application.
- 4a) Of the above claim(s) 25 - 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 24, 41 - 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3-25-2004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Receipt of Applicant's response to Restriction/Election requirement, filed 8/30/2005, along with arguments and remarks therein, is acknowledged.

#### *Response to Arguments*

Applicant elected Group I, claims 1 – 24 with traverse. Applicant argues that the inventions of instant claims can be searched in one Application without undue burden on the office. However, Applicant gives no specific reason as to why there would not be a burden. Examiner has already pointed out reasons why the Groups are patentably distinct. Applicants argument is therefore not entirely persuasive.

Upon consideration, Examiner is withdrawing the restriction requirement between Groups I and IV. Groups IV is rejoined to group I, and both will be examined in this application. Examiner also notes that some of the Claims of Group III are process claims that are dependant on product claims in Group I. Note the following guidelines which state, in part, that Applicant may be entitled to a rejoinder of some of the claims of Group III if and when the Claims of Group I are found allowable. If and when the claims of Group I are found allowable, Examiner will consider a request by Applicant to rejoin the claims of Group III that depend from those of Group I, as in the following guidelines.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Pending Claims***

Claims 1 – 24 and 41 – 48 are currently pending in this action.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1 – 3, 9, 12, 13, and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 - 13 of copending Application No. 10/326339. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant and copending claims are each drawn to compositions containing the same bone-derived materials (soluble and insoluble materials, including powders), and the same polymers. Instant claim 21 has additional components that are included in copending claim 13. The claims are worded somewhat differently, but the artisan would understand them to mean essentially the same thing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 15, 20, 21, 22, 41 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clokie, US 6,309,659 of record, in view of Zhang et al. US 6,232,340.

Clokie teaches a composition containing a polyethyleneoxide-polypropylenepoxide-polyethyleneoxide block copolymer bone powder (col. 1) which may be demineralized or not (col. 2, line 67) and a solvent (col. 1). The solvent may be

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water (Example 2). A person of ordinary skill in the art would recognize that mineralized bone powder contains materials extractable from bone. This composition exhibits reverse phase behavior (col. 4, lines 83 – 65). Clokie further discloses that the composition contains a therapeutic material. As exemplary therapeutic materials, Clokie mentions osteoinductive and osteoconductive materials, as well as materials that are both osteo-inductive and conductive. Specifically mentioned are TGF- $\beta$  types 1 – 13, and bone morphogenetic protein types 1 – 15 (paragraph bridging col.'s 2 and 3). Other exemplary materials for inclusion in the composition are gypsum, hydroxyapatite, calcium carbonate, calcium phosphate, and calcium sulfate. Clokie discloses that the weight percentage of the components can be varied (paragraph bridging col.'s 4 and 5).

The differences between the teachings of Clokie and instant claims are:

(1) Clokie does not teach the precise proportion of the compositions of all of instant claims; and,

(2) The block copolymer disclosed by Clokie is identical to that of instant claims in all respects except that the copolymer of Clokie contains PEG that does not have methyl groups, whereas the copolymer of instant claims has methyl terminated PEG.

Zhang discloses materials and compositions for therapeutic uses, including treatment of bone destruction (col. 2, lines 30 – 35). Zhang further discloses that these compositions may include polyethylene glycol copolymers, wherein the polyethylene glycol component may be either methyl terminated (MePEG) or not (PEG).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the methyl terminated copolymer of instant claims instead of

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the copolymer of Clokie. The motivation to do so comes from Zhang, who teaches that MePEG copolymers and PEG copolymers are equivalents in the art. Therefore, absent an unexpected result stemming from polymer end-caps, this manipulation is deemed to be substitution of art-recognized equivalents, and thus, the artisan would have a reasonable expectation of success.

The motivation to use the component ratios of instant claims comes from Clokie, who teaches that the component ratios can be varied in order to achieve the best possible result. Since this is an explicit teaching, it follows that such manipulations are within the ken of the artisan, who would have a reasonable expectation of success at doing so.

Claims 16 – 19, 22 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clokie, US 6,309,659 of record, in view of Zhang et al. US 6,232,340 as applied to claims 1 – 15, 20, 21, 22, 41 – 48, above, and further in view of Sierra et al, US 5,290,552.

The teachings of Clokie and Zhang are discussed above.

Clokie and Zhang do not teach the use of bone chips.

Sierra teaches a surgical material. Sierra teaches that for dental or orthodontic or dental applications it is preferable to include bone powder and bone chips in surgical materials (col. 5, lines 24 – 27).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to add bone chips to a composition for orthodontic use, since Sierra teaches them as preferable components of such compositions. The expected

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result would be an effective material to treat damaged bone. Since these manipulations are known in the art, the artisan would have a reasonable expectation of success.

***Conclusion***

No claims are allowed. No claims are free of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1615



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